

SIGNIFICANT LEGISLATIVE RULES ANALYSIS
For Rules Concerning Childbirth Centers
Chapter 246-329 WAC

Briefly describe the proposed rule.

The proposed rules outline the minimum public health and safety standards for the licensure and operations of Childbirth Centers (CBC) in Washington State.

Minor Changes:

- Condense and clarify wording, grammar, structure and formatting
- Clarify requirements for licensing, reporting, documentation and compliance
- Remove issues unrelated to public health
- Update terminology to reflect current usage

Changes Easing Requirements:

The entire process involved the interested party community. The purpose was to more clearly state the rules for ease of use and understanding. Required processes were more clearly stated to reflect the standard of practice within Washington State and nationally. Expert input, as well as national childbirth standards, were utilized when appropriate.

Changes Imposing Additional Requirements:

- Develop and implement written policies and procedures governing emergency preparedness and fire protection to align with standards for other like health care facilities.
- Maintain a quality improvement program to assure the quality of care and services provided result in continuous improvement of client health outcomes. Quality improvement requirements were stated in current rule, but the newly proposed requirements are more clearly stated and reflect contemporary standards for other like health care facilities.
- Provide each client with a written bill of rights, verified by client or representative signature, affirming each individual's rights and to align with standards for other like health care facilities.
- Notify and submit a written report to the department in the event of unanticipated death or loss of function, abduction or discharge to the wrong family, sexual assault or rape, or a catastrophic event to align with standards for other like health care facilities.

Other Components of the Rule:

- Allows birthing centers built before the adoption of proposed rules to be maintained to the standards that were in place at the time the facility was licensed.

Modified or altered areas shall be maintained to the standards in place at the time that the modification or alteration was made, and in accordance with the approved plans.

Is a Significant Analysis required for this rule?

Yes, portions of this rule require a significant analysis. The significant portions of the proposed rule are discussed in this analysis. Other portions of the rule are not significant and are therefore not included in the analysis.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The objective of chapter 18.46 RCW is to provide for the development, establishment, and enforcement of standards for the maintenance and operation of birthing centers, which, in the light of advancing knowledge, will promote safe and adequate care and treatment of the individuals therein. The objective of drafting rules under RCW 18.46.060 is to promote safe and adequate medical and nursing care in the birthing center and the sanitary, hygienic, and safe condition of the birthing center in the interest of the health, safety and welfare of the people.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

The Department believes that the provisions proposed in these rules are the minimum necessary to ensure safe and adequate treatment, safe and adequate medical and nursing care, and the sanitary, hygienic, and safe condition of the birthing center.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the rule that are significant are analyzed in the numbered list below. As discussed above, other portions of the rule are not significant and are therefore not included in this analysis.

Rules with no significant impact	Justification
246-329-005	RCW 34.05.328(5)(b)(iv) Clarification
246-329-010	RCW 34.05.328(5)(b)(iv) Clarification
246-329-030	The rules are procedural, relating to application requirements for licensure. RCW 34.05.328(5)(b)(iv) Clarification
246-329-055	The rules are procedural, relating to application requirements for licensure. RCW 34.05.328(5)(b)(iii) Adopts current state law
246-329-065	RCW 34.05.328(5)(b)(iii) Adopts current state law
246-329-095	RCW 34.05.328(4)(b)(iv) Clarification
246-329-130	RCW 34.05.328(5)(b)(iv) Clarification
246-329-150	RCW 34.05.328(5)(b)(iv) Clarification
246-329-990	RCW 34.05.328(5)(b)(vii). Sets or adjusts fees

The Department of Health made every effort to mitigate any additional costs for childbirth centers throughout the rulemaking process. The department has also found that most childbirth centers already meet or exceed the proposed additional requirements; for those centers, additional costs will be nominal. The purpose of any additional requirement is to ensure the health and safety of the clients as well as the personnel of the centers. Additional requirements also align the standards for childbirth centers with the standards for like health care facilities. Throughout the rulemaking process, stakeholders agreed that any additional requirements were, indeed, in the best interest public health and safety.

Proposed rules sections with probable fiscal impact: These sections may impose an additional cost to all thirteen childbirth centers in Washington State. Additional costs are estimated by the number of employees in each center (ranging from one to six employees).

Significant WAC rules with fiscal impact	Affects
246-329-085	The health and safety benefits outweigh the cost associated with the proposed rule.
246-329-110	The health and safety benefits outweigh the cost

246-329-120	associated with the proposed rule. The health and safety benefits outweigh the cost associated with the proposed rule.
246-329-140	The health and safety benefits outweigh the cost associated with the proposed rule.
246-329-170	The health and safety benefits outweigh the cost associated with the proposed rule.
246-329-180	The health and safety benefits outweigh the cost associated with the proposed rule.

Client Bill of Rights (WAC 246-329-085)

Description: Under the proposed rule, a licensee must provide a patient with a written bill of rights that must be verified by the patient. The purpose of the bill of rights is to help improve patient outcomes by respecting each client and conducting all relationships with clients and the public in an ethical manner. The bill of rights includes information such as services provided by the birth center, other maternal/fetal/newborn services available, emergency transfer information, and complaint information.

Analysis: Associated costs are the time and resources needed to generate a list of appropriate information regarding patient rights. Informing patients of their rights has been a standard of practice in facilities, particularly since 2SSB 6199, Health Care Patient Bill of Rights, was passed in 2000. The department assumes a manager would need 16 hours to create a bill of rights. At \$32 per hour, the cost would be \$512. The benefits of clients knowing their rights and options outweigh the costs associated with the proposed rule.

Emergency Preparedness (WAC 246-329-170)

Description: Under the proposed rule, a licensee must establish and implement a written disaster plan designed to meet both internal and external disasters, to include emergency preparedness and fire protection. Training must be conducted and rehearsed periodically with personnel, contactors, and volunteers to follow in the event of an internal or external emergency or fire. Semiannual evacuation and fire drills for each shift of personnel must be conducted.

Analysis: The associated costs are the time and resources needed to generate and maintain the written emergency preparedness and fire protection plans. The licensee must also conduct training. The nature of the plans will depend on the size of the facility.

DOH will make the assumption that policies and procedures developed by the licensees for emergency preparedness and fire protection will be incorporated into a single plan. DOH also estimates that the basic plan will take a manager one to four hours to complete at an estimated hourly wage of \$32, for a total cost of \$32 to \$128. The initial training of personnel, contractors and volunteers will take two hours, for a total of \$64. The semi-annual evacuation and fire drills should not impose a cost.

The benefits of having an emergency preparedness plan are increased emergency preparedness. Emergency preparedness assured newborn and maternal client safety and health needs are recognized and addressed in emergency situations. Without a plan, childbirth center staff may not understand how to react in an emergency, and the lack of preparation potentially risks the health and safety of the residents. These benefits outweigh the costs associated with requiring an emergency preparedness plan.

Rule sections with potential fiscal impact. These sections may or may not impose a fiscal impact on childbirth centers. Cost estimates vary depending on the number of employees in a childbirth center (ranges from one to six employees).

Personnel Policy and Procedures and Records (WAC 246-329-110)

Description: The proposed rules require birth centers to establish and implement policies and procedures to ensure they provide direction and standards in the employment, contracting and recording of personnel procedures. This includes developing job descriptions for employees, contractor agreements and volunteer responsibility statements; verification of clinical staff credentials; orientation to policies and procedures; cardiopulmonary resuscitation training; infection control practices, Tuberculosis screening and Hepatitis B vaccination. Verification of appropriate education and training, performance evaluations and criminal background inquiries and communicable disease testing must be maintained in employee, contractor, student and volunteer records.

Analysis: Any associated costs are the time and resources needed to generate and maintain the written job descriptions for employees, contractor agreements, volunteer responsibility statements and agreements with students commensurate with responsibilities and consent with professional credentialing and scope of practice. The licensee must also orient clinical staff to policies and procedures. The number of job descriptions will depend on the number of employees. Many childbirth centers have similar policies and procedures in place.

DOH will make the assumption that job descriptions for all staff will take a manager two hours to complete for a center with one employee and up to 10 hours to complete for a center with six employees. At an estimated hourly wage of \$32, the total cost ranges from \$64 to \$320. The initial training of clinical staff will take one to four hours, for a total of \$32 to \$128.

The benefits of having a clear description of job responsibilities will ensure staff is working within their scope of practice. Without a clear description, employees may work beyond their appropriate scope and endanger to health of the birth center clients. These benefits outweigh the costs associated with requiring an emergency preparedness plan.

Other changes within this section reflect current requirements of other rules or statutes.

Birth Center Policies and Procedures (WAC 246-329-120)

Description: The proposed rules describe the policies and procedures the birth center must establish and implement to ensure safe and appropriate care to its clients. In addition to policies and procedures already in rule, a birth center must establish written plans for consultation, referral and transfer; protocol for medications and laboratory testing; protocols for immunizations and monitoring; 24 hour availability of transfer; and informed consent. The birth center must provide or assure collection of newborn screening, rapid HIV testing, Hepatitis B immunizations for positive women, actions to take when personnel exhibit or report symptoms of communicable disease, authorization and administration of medications, reporting patient abuse, actions in the event of death or emergency.

Analysis: Any costs associated with this section would be the cost of developing policies and procedures to implement this section. DOH will make the assumption that policies and procedures will take a manager 10 hours to complete at an estimated hourly wage of \$32, for a total cost of \$320. The benefits of having clear policies and procedures will ensure staff has a clear description of what is required to provide safe and appropriate care. These benefits outweigh the costs associated with requiring policies and procedures.

Other changes within this section reflect current requirements of other rules or statutes.

Client Records (WAC 246-329-140)

Description: The proposed rule requires the licensee to maintain records in order to obtain, manage and use information to improve patient outcomes and the performance of the birth center in patient care. The licensee is required to maintain records for adults for three years after the date of termination of services. Records for minors must be maintained for three years after attaining age 18, or five years following discharge, whichever is longer.

Analysis: Childbirth centers are currently required to have a defined client record system, policies and procedures. The proposed rule clarifies the type of documentation required. Any costs associated with this section are the time and resources required by the specified retention period. The department assumes most centers have record space available for the already required record storage. If additional space was necessary, a new three-drawer locking filing cabinet would cost approximately \$500, including tax. Maintaining medical records for a period of time provides access to important medical

information necessary to ensure continuity of care. Accessible information could be invaluable in an emergent situation. The benefits of establishing a requirement to maintain information outweigh the costs associated with the proposed rule.

Quality Improvement (WAC 246-329-180)

Description: Under the proposed rules, licensees must ensure that performance improvement activities of clinical staff result in continuous improvement of client health outcomes. Quality improvement programs must include, at a minimum, a complaint process; methods to identify, monitor and evaluate services, referrals, complications of pregnancy and other aspects of service; methods to identify, evaluate, monitor and correct problems identified by clients or staff or corrective actions taken; and a system to address client satisfaction.

Analysis: The department assumes that most licensed facilities currently practice a facility wide approach to process design, performance measurement, assessment, and improvement (coordinated quality improvement program (CQIP). The associated costs are the time and resources needed to establish and implement a program, subject to the size of the facility. The department estimates the cost for establishing a program based on an hourly wage of \$32 multiplied by six hours, or a total of \$192.

The benefits of a quality improvement program for the purpose of improving the quality of health care and identifying and preventing health care malpractice outweigh the cost of adopting the rule.

The following sections do not impose additional cost.

Significant WAC rules with no fiscal impact	Affects
246-329-020	Clarifies current practice and adopts current requirements of other entities
246-329-025	Clarifies current practice
246-329-045	Clarifies current practice
246-329-075	Clarifies requirements of RCW 43.43.830 through RCW 43.43.845
246-329-160	No cost to existing facilities

Licensure (WAC 246-329-020)

Description: The proposed rule establishes the information the licensee must provide to the department for licensure and renewal. It requires that applications for renewal shall be on forms provided to the department and filed with the department no less than 30

days prior to expiration. It also requires that disclosure statement and criminal background checks no older than three months preceding the renewal date for the administrator, owner and director of services when these individuals are new to the facility since initial licensure or last renewal, accompany the renewal.

Subsection (3) requires a 30 day notice of change of ownership. Both the licensee and prospective owner must submit in writing specific information to the department. The prospective owner must submit a change of ownership fee of \$150.

Analysis: The proposed rule does not impose additional cost to the licensee. The licensure and renewal requirements adopt current department practice, or already requirements of other entities. Disclosure statements and criminal history background checks are current requirements. The 30 day requirement is current department practice with other facility types. It allows the department sufficient time to review applications to ensure there are no deficiencies at the time of renewal. Complete information ensures that childbirth centers are in compliance with requirements of the department and other regulating entities. Any costs associated with the proposed rule outweigh the cost of adopting the rule.

A prospective new owner must submit a fee of \$150. This fee is charged as current practice with most facility types. It meets the requirement of RCW 43.70.250, which requires the department to charge fees to cover the cost of program operation, and RCW 34.05.328(5)(b)(vi) which exempts rules that set fees.

Exemptions, Alternative Methods, and Interpretations (WAC 246-329-025)

Description: Under the proposed rule, an applicant or licensee may request in writing an interpretation, exemption, or approval to use an alternative method. Requests for exemption must specify the section or sections, explain the reason for the exemption, and include supporting documentation when appropriate. Requests for alternative methods must explain the reason for the use of an alternative and must be supported by technical documentation. Requests for interpretations of rule must specify the sections for which an interpretation is needed and circumstances to which the rule is being applied. The department must send a written interpretation of a rule within 30 calendar days after the department has received complete information relevant to the requested interpretation.

Analysis: There are no associated costs to adopt the proposed rule because the proposed rule clarifies the current practice of the department. The language in the rule adopts the departmental policies on addressing childbirth center exemptions. Operators of childbirth centers and their clients benefit because the proposed rule allows the department and licensees to address alternative methods for meeting the intent of chapter 246-329 WAC without jeopardizing the health and safety of those within the facility.

Applicant or Licensee Rights and Responsibilities (WAC 246-329-045)

Description: The proposed rule clarifies the applicant or licensee's responsibilities in the fulfillment of the requirements of the chapter. This includes addressing the requirements of this chapter; responding to statements of deficiencies; notifying and reporting to the department when events such as unanticipated death, abduction, sexual assault or catastrophic events occur; and right to respond to and contest statements of charges.

Analysis: There are no associated costs to adopt the proposed rule because the proposed rule clarifies the current practice of the department. The language in the rule adopts the departmental requirements for childbirth centers to fulfill certain responsibilities. The public will benefit because the department will be informed of events in which the interest of the public will be reviewed to determine if there is an immediate danger of public harm. Operators of childbirth centers and their clients benefit because the proposed rule describes what they must do to fulfill their requirements for licensure.

Criminal History, Disclosure, and Background Inquiries (WAC 246-329-075)

Description: The proposed rule specifies that the childbirth center applicant or licensee must establish and implement policy and procedures regarding criminal background inquiries and disclosure statements for the administrator, owner, director of services and personnel, contractors, volunteers, students, and any other individual associated with the childbirth center having direct contact with children under 16 years of age, people with developmental disabilities or vulnerable adults.

Analysis: Requiring the personal criminal history, disclosure and background inquiry documentation for staff, independent contractors, contractors, volunteers and students clarifies the facilities responsibility to ensure that all staff providing direct care are eligible to provide services to vulnerable adults and children. There are no new costs to adopt the proposed rule; childbirth centers currently require background checks. The proposed rule clarifies the responsibility of the licensee to follow current state laws concerning vulnerable adults and children under RCW 43.43.830 through RCW 43.43.845.

Birth Center -- Physical Environment (WAC 246-329-160)

Description: The proposed rule requires the licensee to provide a safe and clean environment in order to reduce and control environmental hazards and risks, prevent accidents and injuries, and maintain safe conditions and equipment for clients, visitors and staff. The proposed rule is very similar to the original rule, but adds clarification in areas such as room size and water temperature.

Analysis: There should be no cost associated with this section of the rule. Since the rule allows birthing centers built before the adoption of the proposed rules to maintain standards that were in place at the time the facility was licensed, no physical changes would be required for existing facilities. The original rule required a birthing room to be adequate and appropriate to provide for equipment, staff, supplies and care of the

maternal client, her support persons, and the newborn during birth, labor and recovery. 300 feet answers the question of what adequate space means. Water temperatures simply state current agency standards and practice. The benefits of establishing requirements in response to current practices outweigh any potential costs of the proposed rule.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

DOH staff worked closely with constituents and the public to minimize the burden of this rule. The department notified all licensees and stakeholders when it first started developing the rule. Interested parties were invited to participate in a stakeholder workgroup. Five stakeholder workgroup meetings were held in Olympia, Washington. The department also sought comment on draft language throughout the rule development process.

In the course of these and other efforts, the following alternative version(s) of the rule were rejected:

Alternative version for proposed rule change to WAC 246-329-120 (1)(e): Written plans for consultation, referral and transfer of care for maternal client and newborns. The alternative version a lengthy list of indications for consultation, including lists of preexisting, antepartum, intrapartum, postpartum and neonatal conditions.

Compared to this alternative version, the proposed rule (which excludes the listings altogether) is less burdensome for those required to comply with it because it simply requires providers to work within their scope of practice and allows flexibility for the care centers that provide varied staffing levels.

Alternative version for proposed rule change to WAC 246-329-020(1): This subsection included a requirement for licensees to submit evidence of current birth center liability insurance in the amount of one hundred thousand dollars per occurrence and public liability and property damage insurance in the amount of two hundred thousand per occurrence as a minimum. WAC 246-329-020(2) required evidence of continuing insurance coverage.

Compared to this alternative version, licenses the proposed rule is less burdensome for those required to comply because licensees are not required to provide proof of liability insurance, nor is it within the authority of the department to set liability limit requirements.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities. For child birth centers, all entities are private.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.